

REMARKS

Claims 1-20 are presently pending in the present application, with claims 5, 10, 11, and 17-20 having been withdrawn in connection with a prior restriction requirement. Thus claims 1-4, 6-9, and 12-16 have been examined. Claims 1, 15 and 16 have been amended herein for clarification. No new matter is presented by these amendments.

§102(b) Rejection - U.S. Patent No. 5,242,460

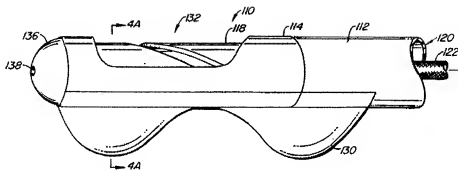
The Office Action rejected claims 1, 3, 6-9, and 12-16 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,242,460 to Klein et al ("Klein").

Claim 1

Claim 1 has been amended for clarification and is reproduced below (with emphasis added):

1. A catheter for insertion into a biological conduit comprising:
 - an elongate catheter shaft having a proximal end and a distal end, the catheter shaft comprising:
 - a material collection chamber located within the catheter shaft, and
 - a controllably arcuate segment configured to selectively transition between a relatively straight shape and a bowed shape, the arcuate segment defining an opening in the form of a hole that is located at a convex portion of the controllably arcuate segment when the controllably arcuate segment takes the bowed shape, wherein a portion of the controllably arcuate segment having the opening is configured to maintain a substantially constant cross section throughout the transition; and
 - a sliding member movably disposed within the shaft and configured to selectively traverse the opening to move a material received through the opening into the material collection chamber and away from said opening.

All of the elements cited in the Office Action as anticipating the catheter of prior claim 1 are in Klein's FIG. 1, shown in part below.



The Office Action states that Klein's *cylindrical housing 114* along with balloon 130 anticipate the "controllably arcuate segment ..." of prior claim 1. Klein indicates that balloon 130 can be inflated and that the cutting head 118 can be rotated, but never states or shows that its *cylindrical housing 114* is controllably arcuate. The Advisory Action, however, states that "any balloon is controllably arcuate ... when a balloon is in an inflated state it has an arcuate shape."

Claim 1 has been amended to further clarify aspects of the "controllably arcuate segment." In particular, with respect to Klein, it is clarified that claim 1 requires that its controllably arcuate segment configured to:

selectively transition between a relatively straight shape
and a bowed shape

As shown in FIG. 1 of Klein, if the balloon 130 is considered part of Klein's controllably arcuate segment, then Klein does not have a "relatively straight shape" when not inflated. Further, Applicant also contends that the combination of Klein's cylindrical housing 114 and balloon 130 do not take a bowed shape when balloon 130 is inflated. Rather, cylindrical housing 114 does not change shape and balloon 130 takes a bulb shape. In any event Klein's cylindrical housing 114 and balloon 130 do not transition between a relatively straight shape and a bowed shape, as in claim 1.

Additionally, with respect to the controllably arcuate segment, claim 1 requires that:

the controllably arcuate segment defining an opening in the
 form of a hole that is located at a convex portion of the

controllably arcuate segment when the controllably arcuate segment takes the bowed shape,

If Klein's balloon 130 is the "controllably arcuate segment" than it certainly is not taught with a hole in a convex portion of the balloon. Not only does Klein not teach a hole in a convex portion of balloon 130, a hole in the balloon 130 would not enable the balloon to inflate. Thus, Klein does not teach a hole in a convex portion of a bowed shape taken by the controllably arcuate segment, as in claim 1.

Additionally, with respect to the controllably arcuate segment of claim 1, Klein does not teach:

a portion of the controllably arcuate segment having the opening is configured to maintain a substantially constant cross section throughout the transition

Again, if Klein's balloon 130 is a controllably arcuate segment, it does not maintain a substantially constant cross section throughout a transition from a relatively straight shape and a bowed shape. Because as the balloon 130 is inflated its cross section expands as it is filled.

Therefore, for several reasons, claim 1 is not anticipated under 35 U.S.C. §102(b) by Klein. Accordingly, Applicant requests reconsideration and withdrawal of the rejection to claim 1.

Claims 3, 6-9, and 12-16

With respect to claim 3, as with claim 1 from which it depends, Klein does not anticipate the catheter of claim 3, which further comprises "an aspiration chamber near the proximal end, said aspiration chamber in fluid communication with the material collection chamber." Accordingly, Applicant requests reconsideration and withdrawal of the rejection of claim 3.

With respect to claim 6, as with claim 1 from which it depends, Klein does not anticipate the catheter of claim 6, "wherein the material collection chamber is proximal to

the controllably arcuate segment.” Accordingly, Applicant requests reconsideration and withdrawal of the rejection of claim 6.

With respect to claim 7, as with claim 1 from which it depends, Klein does not anticipate the catheter of claim 7, which further comprises “a material extraction lumen between the distal end of the catheter shaft and an aspiration port located on the proximal portion of the device.” In fact, the Office Action offers no showing of an aspiration port in Klein, which is required by claim 7. Since Klein teaches away from aspiration of the material, e.g., in col. 4 lines 28-34:

Severed atheromas will be largely retained within the cutting head until they can be withdrawn from the patient, thereby affording means for withdrawing the material that does not require aspiration and the design complexities that accompany use of aspiration means.

Accordingly, Applicant requests reconsideration and withdrawal of the rejection of claim 7.

With respect to claim 8, as with claim 1 from which it depends, Klein does not anticipate the catheter of claim 8, “wherein the controllably arcuate segment has a normally bowed bias.” In addition to the comments provided above with respect to claim 1, Klein does not discuss the arcuate segment having a *normally bowed bias*, as in this claim. In fact, Klein’s cylindrical shaft 114 is never shown or described as being bowed. And balloon 130 appears to have no bias, since it is malleable in its normally inflated state. Accordingly, Applicant requests reconsideration and withdrawal of the rejection of claim 8.

With respect to claim 9, as with claim 8 from which claim 9 depends, Klein does not anticipate the catheter of claim 9, “wherein positioning of the sliding member within the controllably arcuate segment causes said arcuate segment to be relatively straight.” Accordingly, Applicant requests reconsideration and withdrawal of the rejection of claim 9.

With respect to claim 12, as with claim 1 from which it depends, Klein does not anticipate the catheter of claim 12, “wherein the sliding member has a cutting edge on the end facing the opening in the controllably arcuate segment.” In fact, in Klein cutting head 118 is taught as being rotational – not configured for sliding. (see, e.g., Klein col. 5, lines 13-17; col. 7, lines 16-20) Accordingly, Applicant requests reconsideration and withdrawal of the rejection of claim 12.

With respect to claim 13, as with claim 1 from which it depends, Klein does not anticipate the catheter of claim 13, “wherein the sliding member is attached to a flexible shaft, said shaft traversing the length of the catheter and said sliding member advanced and retracted by advancing and retracting said shaft from controls located on the proximal end of said catheter.” In fact, the Office Action never offered any citation within Klein to show “said shaft traversing the length of the catheter and said sliding member advanced and retracted by advancing and retracting said shaft from controls located on the proximal end of said catheter” of claim 13. Accordingly, Applicant requests reconsideration and withdrawal of the rejection of claim 13.

With respect to claim 14, as with claim 1, Klein does not anticipate the catheter of claim 14, which further comprises “a rotational orientation element.” Accordingly, Applicant requests reconsideration and withdrawal of the rejection of claim 14.

Claims 15 and 16

Applicant requests removal of the rejections under 35 U.S.C. 102(b) to claims 15 and 16 as being anticipated by Klein. The Office Action offered no text that states how Klein anticipates each and every element of independent claim 15 and its dependent claim 16.

Independent claim 15 has been amended in a manner similar to that of claim 1. Thus, claim 15 has elements similar to those discussed above with respect to claim 1, so is similarly not anticipated by Klein. For example, as discussed with respect to claim 1,

Klein does not anticipate a catheter having a *controllably arcuate segment* of a catheter shaft.

Claim 15 also includes elements not in claim 1 and never addressed in the Office Action, nor are they present in Klein. Specifically, nowhere does the Office Action address how Klein anticipates the “aspiration port configured to receive a vacuum input” or “an aspiration lumen configured to form a vacuum path” of claim 15. As a result, it has not been shown that, with respect to claims 15 and 16, “the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States” as required under 35 U.S.C. 102(b).

In fact, as noted above with respect to claims 1 and 7, Klein teaches away from aspiration of the removed material – explicitly opting to retain within the cutting head until removal of the catheter from the patient’s body.

Therefore, for several reasons, Applicant respectfully requests withdrawal of the rejection to claim 15.

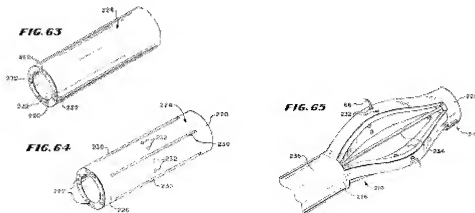
With respect to claim 16, which depends from claim 15, Klein does not anticipate the catheter of claim 16, which further comprises “a sliding member movably disposed within the shaft and configured to selectively traverse the opening to move the material received through the opening away from said at least one opening and toward the aspiration chamber.”

As discussed above with respect to claim 1, the *rotating* cutting head 118 of Klein in not a *sliding* member. Also, as noted above the Office Action did not present any ground for rejecting this claim. Accordingly, for several reasons, Applicant requests reconsideration and withdrawal of the rejection of claim 16.

§102(b) Rejection - U.S. Patent No. 6,326,798

The Office Action rejected claims 1-4, 6-9, and 12-16 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,326,798 to Edwards et al. (“Edwards”).

The Office Action cited FIG. 65 of Edwards as anticipating claim 1. FIG. 65 is the 3rd in a series of three figures (63-65) that disclose Edwards' basket structure - cited as teaching the controllably arcuate segment of claim 1, and formation thereof. These three figures are reproduced below for convenience.



Specifically, the Office Action asserted that the controllably arcuate segment of claim 1 is taught by the extruded basket structure 218 and the sliding member is taught by wire 234 of Edwards. In the Advisory Action it was stated that "each strip that makes up the basket element (218) is capable of assuming an arcuate shape." Applicant contends, however, that it is the overall shape of basket 218 that is relevant, not individual parts of the basket – and the overall shape of basket 218 is not arcuate or bowed (as in amended claim 1).

Fundamentally, the device of Edwards is structured to deploy a carrier of an electrode that can be advanced to penetrate tissue. (See *Edwards*, Abstract), as opposed to the catheter of claim 1 which is structured to remove a material.

Additionally, claim 1 has been amended for clarification, particularly with regard to the controllably arcuate segment. It should now be clear that basket 218 of Edwards does not anticipate the following element from amended claim 1:

a controllably arcuate segment configured to selectively transition between a relatively straight shape and a bowed shape, the arcuate segment defining an opening in the form of a hole that is located at a convex portion of the controllably arcuate segment when the controllably arcuate segment takes the bowed shape, wherein a portion of the

controllably arcuate segment having the opening is configured to maintain a substantially constant cross section throughout the transition;

Basket 218 of Edwards, does not for example, maintain a substantially constant cross section through a transition from a relatively straight shape to a bowed shape – as required by amended claim 1. Rather, the cross section of basket 218 in Edwards expands as the basket is opened, as in FIG. 65.

And, as mentioned above, the extruded basket structure 218 of Edwards is bulb-shaped (as shown in FIG. 65), not bowed. Individual members of the extruded basket structure 218 may individually have an arc shape, but the overall shape of the extruded basket structure 218 is of a bulb – not bowed. Thus, in Edwards, the segment of the shaft having the extruded basket structure 218 is bulb-shaped – not bowed as required by claim 1.

Additionally, the wire 234 of Edwards is not the sliding member of claim 1 as suggested in the Office Action, the relevant element is reproduced below:

a sliding member movably disposed within the shaft and configured to selectively traverse the opening to move a material received through the opening into the material collection chamber and away from said opening.

For example, the wire 234 does not “traverse,” i.e., travel across or pass over, an opening. It merely travels down a central axis of the catheter tube 236 and basket 218. So wire 234 does not traverse an opening.

Also, the wire 234 in Edwards is merely used to pull the distal end of basket 218 toward the catheter tube 236 (described in Edwards, col. 26, line 47 through col. 27, line 24), so that the extruded basket structure 218 can be formed from the extruded tube in Edwards’ FIGS. 63 and 64. For example, compare the simple wire 234 of Edwards with the sliding member 100 of FIG. 3 of the present application, as an example. The wire 234 of Edwards cannot move material, it would simply move through material. Clearly, the simple wire 234 of Edwards does not anticipate a “sliding member ... configured to selectively traverse an opening to move a material received through the opening into the material collection chamber and away from said opening.”

Since Edwards teaches a delivery catheter and not a removal catheter, there would be no need for the sliding member of claim 1 in Edwards; and Edwards does not disclose one.

Therefore, for several reasons, amended claim 1 is not anticipated under 35 U.S.C. §102(b) by Edwards. Accordingly, Applicant requests reconsideration and withdrawal of the rejection to claim 1.

Claims 2-4, 6-9, and 12-16

With respect to claim 2, as with claim 1 from which it depends, Edwards does not anticipate the catheter of claim 2, which further comprises “suction means near the proximal end, said suction means in fluid communication with the opening in the controllably arcuate segment.” Accordingly, Applicant requests reconsideration and withdrawal of the rejection of claim 2.

With respect to claim 3, as with claim 1 from which it depends, Edwards does not anticipate the catheter of claim 3, which further comprises “an aspiration chamber near the proximal end, said aspiration chamber in fluid communication with the material collection chamber.” Accordingly, Applicant requests reconsideration and withdrawal of the rejection of claim 3.

With respect to claim 4, as with claim 3 from which it depends, Edwards does not anticipate the catheter of claim 4, which further comprises “further comprising a one-way valve located between the aspiration chamber and the material collection chamber, said valve oriented to allow material to flow from the material collection chamber to the aspiration port.” Accordingly, Applicant requests reconsideration and withdrawal of the rejection of claim 4.

With respect to claim 6, as with claim 1 from which it depends, Edwards does not anticipate the catheter of claim 6, “wherein the material collection chamber is proximal to

the controllably arcuate segment.” Accordingly, Applicant requests reconsideration and withdrawal of the rejection of claim 6.

With respect to claim 7, as with claim 1 from which it depends, Edwards does not anticipate the catheter of claim 7, which further comprises “a material extraction lumen between the distal end of the catheter shaft and an aspiration port located on the proximal portion of the device.” Accordingly, Applicant requests reconsideration and withdrawal of the rejection of claim 7.

With respect to claim 8, as with claim 1 from which it depends, Edwards does not anticipate the catheter of claim 8, “wherein the controllably arcuate segment has a normally bowed bias.” In addition to the comments provided above with respect to claim 1, Edwards does not discuss the arcuate segment having a *normally bowed bias*, as in this claim. In Edwards, the extruded basket structure 218 does not have a normally bowed bias. The opposite is in fact true in Edwards, as demonstrated in Edwards’ FIGS. 63 and 64. The extruded portion is normally cylindrical, but pulled into a bulb shape when the wire 234 is pulled toward the catheter tube 236. Accordingly, Applicant requests reconsideration and withdrawal of the rejection of claim 8.

With respect to claim 9, as with claim 8 from which claim 9 depends, Edwards does not anticipate the catheter of claim 9, “wherein positioning of the sliding member within the controllably arcuate segment causes said arcuate segment to be relatively straight.” Accordingly, Applicant requests reconsideration and withdrawal of the rejection of claim 9.

With respect to claim 12, as with claim 1 from which it depends, Edwards does not anticipate the catheter of claim 12, “wherein the sliding member has a cutting edge on the end facing the opening in the controllably arcuate segment.” Accordingly, Applicant requests reconsideration and withdrawal of the rejection of claim 12.

With respect to claim 13, as with claim 1 from which it depends, Edwards does not anticipate the catheter of claim 13, “wherein the sliding member is attached to a flexible shaft, said shaft traversing the length of the catheter and said sliding member advanced and retracted by advancing and retracting said shaft from controls located on the proximal end of said catheter.” In fact, the Office Action never offered any citation within Edwards to show “said shaft traversing the length of the catheter and said sliding member advanced and retracted by advancing and retracting said shaft from controls located on the proximal end of said catheter” of claim 13. Accordingly, Applicant requests reconsideration and withdrawal of the rejection of claim 13.

With respect to claim 14, as with claim 1, Edwards does not anticipate the catheter of claim 14, which further comprises “a rotational orientation element.” Accordingly, Applicant requests reconsideration and withdrawal of the rejection of claim 14.

Claims 15 and 16

Applicant requests removal of the rejections under 35 U.S.C. 102(b) to claims 15 and 16 as being anticipated by Edwards. The Office Action offered no text that states how Edwards anticipates each and every element of independent claim 15 and its dependent claim 16.

Independent claim 15 has been amended in a manner similar to that of claim 1. Thus, claim 15 has elements similar to those discussed above with respect to claim 1, so is similarly not anticipated by Edwards. For example, as discussed with respect to claim 1, Edwards does not anticipate a catheter having a *controllably arcuate segment* of a catheter shaft.

Claim 15 also includes elements not in claim 1 and never addressed in the Office Action, nor are they present in Edwards. Specifically, nowhere does the Office Action address how Edwards anticipates the “aspiration port configured to receive a vacuum input” or “an aspiration lumen configured to form a vacuum path” of claim 15. As a result, it has not been shown that, with respect to claims 15 and 16, “the invention was

patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States" as required under 35 U.S.C. 102(b).

Therefore, for several reasons, Applicant respectfully requests withdrawal of the rejection to claim 15.

With respect to claim 16, which depends from claim 15, Edwards does not anticipate the catheter of claim 16, which further comprises "a sliding member movably disposed within the shaft and configured to selectively traverse the opening to move a material received through the opening away from said opening and toward the aspiration chamber."

As discussed above with respect to claim 1, the wire 234 of Edwards is not a *sliding* member. Also, as noted above the Office Action did not present any ground for rejecting this claim. Accordingly, for several reasons, Applicant requests reconsideration and withdrawal of the rejection of claim 16.

Closing Remarks

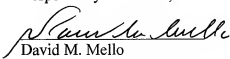
It is submitted that all of examined claims 1-4, 6-9, and 12-16 are in condition for allowance, and such allowance is respectfully requested. Removal of the final rejection and allowance of the above claims is requested.

If prosecution of the application can be expedited by a telephone conference, the Examiner is invited to call the undersigned at the number given below.

Authorization is hereby given to charge Deposit Account No. 501798 for all otherwise unpaid fees due with this response.

Respectfully submitted,

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